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EXAMINER

YABUT, DIANE D

ART UNIT

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3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This action is in response to applicant's amendment received on 08/04/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 7-16, 18-35, 37-42, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) in view of **Mericle** (U.S. Patent No. **5,752,964**).

Claims 7, 15, 18, 24-25, 34, 37 and 62: Atala discloses a suturing instrument comprising a handle **72**, a shaft **66** extending from the handle, the shaft having a proximal end near the handle and a distal end opposite the proximal end, the distal end of the shaft having an opening **93** and a passageway **92** constructed and arranged to carry a suture wire **86** to the opening and to plastically deform the suture wire as the suture wire moves through the passageway to cause the suture wire to form a wire suture loop as the suture wire is extended from the opening in the distal end of the shaft, the passageway and the opening being arranged so that the suture wire extends substantially in a distal direction upon exiting the opening and may loop back to the distal end of the shaft without requiring additional contact with the instrument, a wire

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drive **88** adapted to move the suture wire in the passageway, and a cutter adapted to cut the suture wire at a location near the distal end of the shaft. It is noted that the suturing instrument of Atala is adapted to form the claimed wire suture loop, given that the suture material is a (plastically) deformable wire-like material. Also, regarding Claim 62, the steps of driving deformable suture wire through a passageway in a suturing instrument having a distal end, bending the suture wire in the passageway to form a suture wire loop with suture wire that exits the distal end, the suture wire loop formed without requiring further contact of the instrument to form an annular fastener with the suture wire after the suture wire extends from the distal end of the suturing instrument, and cutting the suture wire to free the suture wire loop from the instrument encompass the same invention of Claim 7, and therefore Atala's device reads on these limitations (Figures 7-9 and col. 5, lines 41-55, col. 7, lines 51-67, col. 9, lines 43-65).

Atala does not expressly disclose that the cutter move into the instrument to free the wire suture loop or annular fastener from the instrument, or a cutter including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut a suture wire.

Mericle teaches a suturing instrument with a cutter **19** including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut the suture wire, which eliminates the need for another instrument such as scissors to cut excess suture material (Figure 4, col. 4, lines 1-28, col. 2, lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a cutter with a cutting surface to move axially along a shaft, as taught by Mericle, to Atala in order to eliminate

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the need for an additional cutting instrument and offer multi-functionality and simplicity for the surgeon.

Claims 8 and 26: Atala discloses the wire drive **88** moving the suture wire **86** through the passageway, a free end of the suture wire exiting the opening in the distal end and following an arcuate, or curved, path **92** whereby the free end may loop or lead back toward the instrument (Figures 7-9, col. 9, lines 43-65).

Claims 9 and 27: Atala discloses the wire drive **88** being adapted to move the suture wire **86** with force sufficient to cause a free end of the suture wire to penetrate tissue (Figures 7-9, col. 9, lines 43-65).

Claims 10 and 28: Atala discloses the cutter being adapted to cut the suture wire so as to form a sharp point on the suture wire (col. 5, lines 41-55).

Claims 11 and 29: Atala discloses the handle having a manually operable actuator adapted to actuate the wire drive (Figures 7-9, col. 7, lines 51-67).

Claims 12 and 30: Atala discloses the cutter being adapted to cut the suture wire to free a portion of the suture wire from the instrument after a length of suture wire is passed through the opening into tissue (col. 5, lines 41-55).

Claims 13 and 32: Atala discloses the suturing instrument being adapted to form the wire suture loop at an extreme axial end of the shaft (Figures 7-9).

Claim 14 and 33: Atala discloses the cutter being adapted to cooperate with a portion of the passageway to cut the suture wire (col. 5, lines 41-55).

Claims 16 and 35: Atala discloses the wire drive being adapted to move the suture wire in an axial direction within the shaft (Figures 7-9, col. 9, lines 43-65).

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Claims 19 and 38: Atala discloses a continuous length of suture wire **86**, wherein the instrument is adapted to form a plurality of wire suture loops from the continuous length of suture wire (Figures 7-9).

Claims 20 and 39: Atala discloses the suturing instrument adapted for use in a minimally invasive surgical procedure (col. 3, lines 30-35).

Claims 21 and 40: Atala discloses the cutter forming part of the passageway (col. 5, lines 41-55).

Claims 22 and 41: Atala discloses the distal end of the shaft including an angled end face (Figures 8-9).

Claims 23 and 42: Atala discloses the suturing instrument arranged to form a wire suture loop in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the passageway such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory (Figures 7-9).

Claim 31: Atala discloses the suturing instrument adapted to form an approximately circular wire suture loop by suture wire that is driven out of the opening in the distal end (Figures 7-9).

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3. Claims 17 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) and **Mericle** (U.S. Patent No. **5,752,964**), as applied to Claims 7 and 24 above, and further in view of **Gordon** (U.S. Patent No. **5,741,277**).

Claims 17 and 36: Atala and Mericle disclose the claimed device except for the passageway including an “S” shaped portion that is adapted to deform the suture wire moving through the “S” shaped portion.

Gordon teaches a suturing instrument with a passageway including an “S” shaped portion that is adapted to deform a suture wire moving through the “S” shaped portion (Figures 39, 41A-41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Atala and Mericle by providing an “S” shaped portion in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for an additional looping, knotting instrument.

4. Claims 43-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al., hereinafter “**Makower**” (U.S. Patent No. **6,090,063**) in view of **Gordon** (U.S. Patent No. **5,741,277**).

Claims 43-61: Makower discloses a handle **7**, a shaft **6** with an angled end face extending from the handle having a distal end with an opening and a passageway adapted to carry a suture wire to the opening, a wire drive **9** adapted to move a suture

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wire axially in the passageway, and a cutter or cutting bar **213** that moves axially along the shaft to cut the suture wire at a location near the distal end of the shaft to free the wire from the instrument. (Figures 1 and 27A-C; col. 7, lines 51-67 and col. 17, lines 1-36). The suture wire extends in a generally distal direction upon exiting the opening, and depending on the type of wire, the wire drive may move the suture wire with force sufficient to penetrate tissue.

Although Makower teaches including or forming a part of the passageway for the suture as seen in Figure 27B, Makower does not expressly disclose the passageway having a curved or "S" shaped portion arranged so that the suture wire moving through and exiting the opening forms suture wire loops

Gordon teaches a suturing instrument with a passageway including an "S" shaped portion that is adapted to deform a suture wire moving through the "S" shaped portion (Figures 39, 41A-41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Makower by providing an "S" shaped portion in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for an additional looping, knotting instrument and to securely attach to tissue. Also, it would have been obvious to one of ordinary skill in the art to provide a cutter bar adapted to cut the suture wire at a location between convex and concave portions, since applicant

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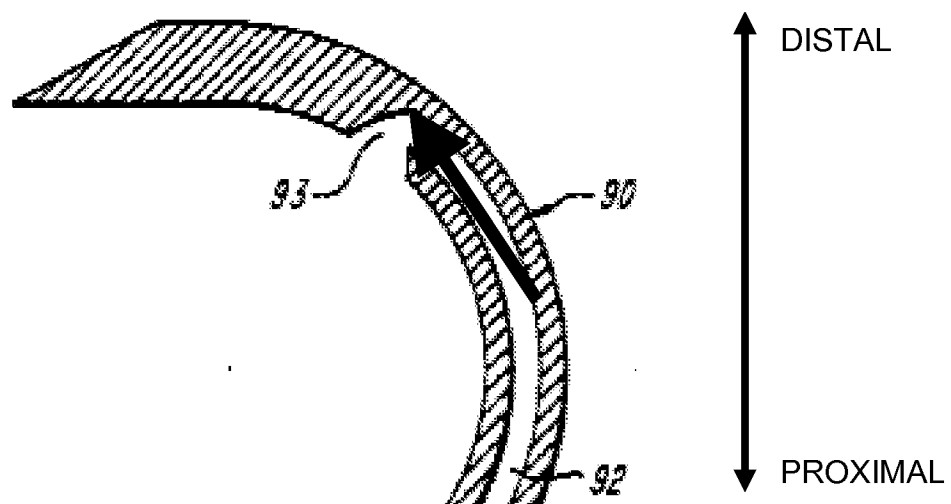
since applicant has not disclosed that cutting specifically between the convex and concave portions solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with this configuration.

Response to Arguments

5. Applicant's arguments with respect to claims 43-61 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's arguments filed 08/04/2008 have been fully considered but they are not persuasive.

7. Applicant generally argues that Atala does not disclose a suture wire extending substantially in a distal direction upon exiting the opening, but rather a suture wire extending sideways. However, the opening may be considered to be the proximalmost end of **93** or distalmost end of **92** (see annotated Figure 8 below) so upon exiting this section, the wire appears to extending substantially distally.



8. Applicant also argues that Atala does not disclose a lateral radius of curvature constructed so that when moved in the passageway, suture wire exits the opening and loops back to the distal end of the shaft along a helical trajectory, or forming a series of loops. However the examiner asserts, as seen in Figures 8-9, that Atala discloses a lateral sideview of an angle of curvature of passageway **92**, which may create loops of suture if a plastically deformable suture wire is passed through the opening for a certain length.

9. Applicant also argues that claim 62 is not disclosed by Atala which requires a method step of bending suture wire in a passageway to form a suture wire loop with a suture wire that exits a distal end of a suturing instrument, the suture wire loop being formed without requiring further contact of the instrument with the suture wire after the suture wire extends from the distal end of the suturing instrument. However, Figure 9 reads on these limitations since a loop is formed in the passageway and the tip of the suture wire exits a distal end of the suturing instrument.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734